		Form Approved. O.M.B. No.	Approval Expires				
	U.S. Food and Drug Administration	AGENCY USE ONLY					
	IFICATION FOR A FOOD ONTACT SUBSTANCE FORMULATION	Date of Receipt					
NOT FOR NE	W USES OF FOOD CONTACT SUBSTANCES						
When completed send this form and notification to	NOTIFICATION CONTROL ASSISTANT OFFICE OF PREMARKET APPROVAL HFS-200 200 C STREET, SW WASHINGTON, D.C. 20204						
Enter the total nu in the Premarket		Date Effective (if effective)	PMF Number				
	GENERAL INSTRUCTIONS	PMF-					

- This form is intended for use only to ascertain that all components of a food contact substance formulation may be legally marketed for their intended use.
- This form may not be used to request authorization for a new use of a food contact substance under section 409(h) of the Federal Food, Drug, and Cosmetic Act. New uses of food contact substances must be the subject of a notification under section 409(h including an FDA Form 3480.
- You should include all information necessary to ascertain that each component of the formulation may be legally marketed for its intended use (technical effect). For example, if the basis for compliance is an effective notification, you should provide information establishing that you may rely on that notification.

Part I — GENERAL INFORMATION

A notification may not be submitted for a formulation unless all of the components of the formulation may be legally marketed for their intended use in contact with food. A notification for a food contact substance formulation should include all information necessary to establish that each compound in the formulation may be legally marketed. For example, additional information necessary to establish that each component of the formulation may be legally marketed for the intended use in contact with food should be attached. Any information referenced in a notification must be submitted to FDA prior to your notification. If you reference information from a third party that is located in other FDA files, provide a letter of authorization for such use, if necessary. For example, authorization is not necessary to reference publicly available information in FDA's files. If third party authorization is required, provide the name of the authorizing official for the third party and a mailing address.

Two copies of your complete notification must be submitted, each with a completed and signed original copy.

Part II — IDENTITY

Provide complete identity information for all components used to produce the food contact substance formulation. If a component (e.g. a reagent or solvent) is completely removed from the formulation as marketed, indicate so. Provide any relevant specifications in order to establish that all components of the formulation may be lawfully marketed.

Part III — INTENDED USE

If possible, use the food types listed in Table 1 of 21 CFR 176.170(c) to describe the types of food the food contact substance formulation will contact in its intended use. If possible, use the time and temperature conditions of use listed in Table 2 of 21 CFR 176.170(c) to describe the time and temperature conditions of use for the food contact substance formulation that is the subject of this notification.

Part IV — LIST OF ATTACHMENTS

Attach additional sheets if there is not enough space to answer a question fully. Label each continuation sheet with the corresponding section heading. List these attachments, any test data or other data and any optional information included in the notification.

OPTIONAL INFORMATION

You may include any information that you want FDA to consider in evaluating this notification.

CONFIDENTIALITY OF INFORMATION

If you are claiming any information in this notification confidential you should submit a redacted copy of the notification. FDA may disagree regarding the disclosability of information claimed confidential.

Provide a sample of the food contact substance formulation as intended for market.

PUBLIC BURDEN STATEMENT

Public reporting burden for this collection of information is estimated to average 20 hours per response, including the time for reviewing instructions, searching existin data sources, gathering and maintaining the data needed, and completing reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to: Food and Drug Administration, Center for Food Safety and Applied Nutrition, Office of Premarket Approval (0910-0014), 200 C Street, SW (HFS-200), Washington, DC 20204. An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number.

Part I — GENERAL INFORMATION														
	Person Submitting Notice	Name of authorized offici	al	Position										
		Company												
		Mailing address (number and street)												
		City, State, ZIP Code, Country												
		Telephone No.	Fax No.		E-Mail Address									
		_												
		Please check here if E-	Mail is your preferred	method of com	munication.									
b.	Agent (if applicable)	Name of authorized offici	al	Position										
		Company												
		Mailing address (number	and street)											
		City, State, ZIP Code, Country												
		<i>J</i> ,,	<u> </u>											
		Telephone No.	Fax No.		E-Mail Address									
		Please check here if E-Mail is your preferred method of communication.												

								Part	II —	- IDI	ENTI	TY											
				Technical Effect	(7)																		
TION			18e,	Basis for	(6)																		
EFORMULA'			number that authorizes use,	CAS Reg No	(5)																		
SUBSTANCI	Section A - IDENTIFICATION OF THE FOOD CONTACT SUBSTANCEFORMULATION Trade or common names Trade or common names 2. Formulation Composition number that authorizes use,	numbe	Maximum	(4)	%	%	%	%	%	%	%	%	%	%	%	%	%	%	%	%	%	%	
D CONTACT		Typical	(3)	%	%	%	%	%	%	%	%	%	%	%	%	%	%	%	%	%	%		
NTIFICATION OF THE FOO				Chemical Name and Manufacturer	Manufacturer (2)																		
Section A - IDE Chemical Identity	Trade or common names	2. Formulation Composition		Chemical Name	Chemical Name (1)																		

Part II — INFORMATION ON IDENTITY, USE AND EXPOSURE — Continued Section A - IDENTIFICATION - Continued b. Characterization List those characteristics of the formulation necessary to verify that the formulation may be lawfully marketed. Polymer Properties Values c. Describe the manufacturing process, including times and temperatures, and include chemical equations for all synthetic steps and side reactions. Describe any purification steps. Mark (X) this box if you attach a continuation sheet.

	Part III — INTENDED USE							
1.	Describe the intended use of the food contact substance formulation, including maximum use levels (or thickness) in food contact materials, and types of food contact articles in which it is expected to be used (e.g., films, coatings, molded articles). State whether single or repeated use is intended. Provide maximum temperatures and times of food contact, refer to classifications in 21 CFR 176.170© Table 2 when possible.							
	Please check here if you attach a continuation sheet.							
2.	List types of food expected to contact the formulation, with examples if known. Refer to classifications in 21 CFR 176.170(c) Table 1 when possible.							
	Please check here if you attach a continuation sheet.							

PHYSICAL AND CHEMICAL PROPERTIES WORKSHEET

To assist FDA's review of physical and chemical properties data, please complete the following worksheet for data you provide and include it in the notification. Identify the property measured, the page of the notification on which the property appears, the value of the property, and the units in which the property is measured (as necessary). The measured properties should be for the food contact substance formulation. You are not required to submit this worksheet.

Property (a)	Mark (X) if provided	Page number (b)	Value ©	Measured or Estimate (M or E)
Physical state of the substance			(s) (l) (g)	
Vapor pressure @ Temperature			Torr	
Density/relative density (specify temperature)			g/cm3	
Solubility @ Temperature Solvent			g/L	
Solubility in water @ Temperature°C			g/L	
Melting Temperature			°C	
Boiling/sublimation temperature @torr pressure			°C	
Spectra				
Dissociation constant				
Particle size distribution				
Octanol/water partition coefficient				
Henry's Law constant				
pH @ concentration				
Adsorption/coefficient				
Other - Specify				
Polymer specific (If a range is applicable, indicate so) % crystallinity of polymer				
Degree of orientation				
Thermal transitions of polymer (i.e., Tg, Tm)				
Density of polymer (specify temperature)				

Part IV — LIST OF ATTACHMENTS

Attach continuation sheets for sections of the form and test data and other data (including physical/chemical properties and structure/activity information), and optional information after this page. Clearly identify the attachment and the section of the form to which it relates, if appropriate. Number consecutively the pages of the attachments. In the column below, enter the inclusive page numbers of each attachment. Notifiers need not list other components of their notification not specifically referenced to this form.

Attachment name	pa	t r(s)	
Mark (X) this box if you attach a continuation sheet. Enter the attachment name and number.			